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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Andrew P. Kloek et al.                      Art Unit : 1652  
Serial No. : 10/082,894                                      Examiner : M. Walicka  
Filed : February 26, 2002  
Title : NEMATODE PGM-LIKE SEQUENCES

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

PETITION TO WITHDRAW NOTICE OF ABANDONMENT

Under 37 CFR §§1.8(b) and 1.181, applicant hereby petitions to withdraw the Notice of Abandonment mailed April 13, 2004 (copy enclosed). The application was abandoned under 37 CFR §1.135 for failure to respond to the Office Action mailed August 12, 2003.

The undersigned, applicant's attorney of record, first became aware of the abandonment on April 15, 2004, upon receipt of the Notice of Abandonment and submits that this petition to withdraw the Notice is being promptly submitted as required by 37 CFR §1.8(b)(1).

The following documents are submitted under 37 CFR §1.8(b)(2) as proof that a Response was timely filed on February 12, 2004:

A copy of the Amendment in Reply to Action of August 12, 2003; a copy of the Petition for Extension of Time; a copy of the check and post card, all of which are dated February 12, 2004.

Also enclosed is a copy of the postcard stamped received by the PTO Mailroom on February 17, 2004.

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date of Deposit

April 29, 2004

Signature

Carrie A. Amonte  
Carrie A. Amonte

Typed or Printed Name of Person Signing Certificate

Applicant : Andrew P. Kloeck et al.  
Serial No. : 10/082,894  
Filed : February 26, 2002  
Page : 2 of 2

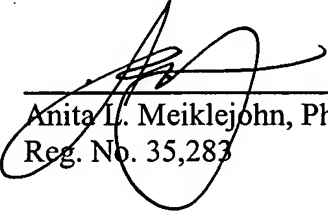
Attorney's Docket No.: 12557-003001

Applicant submits that the response to the Office Action mailed August 12, 2003, was timely filed on February 12, 2004, and requests that the Notice of Abandonment be withdrawn.

Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 28 April 2004

  
\_\_\_\_\_  
Anita L. Meiklejohn, Ph.D.  
Reg. No. 35,283

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225 Franklin Street  
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UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,894	02/26/2002	Andrew P. Klock	12557-003001	2775

26161 7590 04/13/2004

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BOSTON, MA 02110

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EXAMINER

WALICKA, MALGORZATA A

ART UNIT PAPER NUMBER

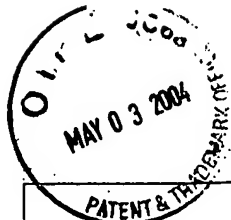
1652

DATE MAILED: 04/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

DOCKETED BY PRACTICE SYSTEMS	
Action Code	<u>Abandonment PTO Error</u>
Base Date	<u>4-13-04</u>
Due Date	
Deadline	<u>6-13-04</u>
Initials	<u>Am</u> On

Processed By Billing Secretary	
Date:	
Deadline:	
Initials:	



# Notice of Abandonment

Application No.

10/082,894

Examiner

Malgorzata A. Walicka

Applicant(s)

KLOEK ET AL.

Art Unit

1652

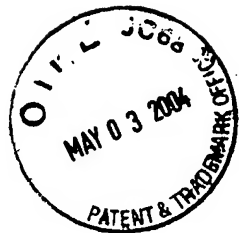
-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

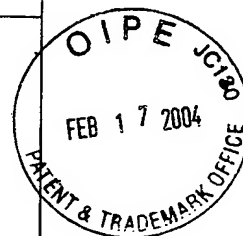
1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on 11 August 2003.
  - (a) ☐ A reply was received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the period for reply (including a total extension of time of \_\_\_\_\_ month(s)) which expired on \_\_\_\_\_.
  - (b) ☐ A proposed reply was received on \_\_\_\_\_, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.  
(A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
  - (c) ☐ A reply was received on \_\_\_\_\_ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
  - (d) ☒ No reply has been received.
2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
  - (a) ☐ The issue fee and publication fee, if applicable, was received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
  - (b) ☐ The submitted fee of \$\_\_\_\_\_ is insufficient. A balance of \$\_\_\_\_\_ is due.  
The issue fee required by 37 CFR 1.18 is \$\_\_\_\_\_. The publication fee, if required by 37 CFR 1.18(d), is \$\_\_\_\_\_.
  - (c) ☐ The issue fee and publication fee, if applicable, has not been received.
3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
  - (a) ☐ Proposed corrected drawings were received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the period for reply.
  - (b) ☐ No corrected drawings have been received.
4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.
5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.
6. ☐ The decision by the Board of Patent Appeals and Interference rendered on \_\_\_\_\_ and because the period for seeking court review of the decision has expired and there are no allowed claims.
7. ☐ The reason(s) below:

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Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.



Attorney's Docket No. 12557-003001	Express Mail Label No.	Mailing Date February 12, 2004	<b>For PTO Use Only</b> <i>Do Not Mark in This Area</i>
Application No. 10/082,894	Filing Date February 26, 2002	Attorney/Secretary Init ALM/caa	
Title of the Invention NEMATODE PGM-LIKE SEQUENCES			
Applicant Andrew P. Kloek et al.			
Client Reference No. PGM			
Enclosures ·Amendment (9 pages) ·Check in the amount of \$475.00 ·Petition for Extension of Time (3 months)			



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Attorney's Docket No. 12557-003001	Express Mail Label No.	Mailing Date February 12, 2004	<b>For PTO Use Only</b> <i>Do Not Mark in This Area</i>
Application No. 10/082,894	Filing Date February 26, 2002	Attorney/Secretary Init ALM/caa	
Title of the Invention NEMATODE PGM-LIKE SEQUENCES			
Applicant Andrew P. Kloek et al.			
Client Reference No. PGM			
Enclosures ·Amendment (9 pages) ·Check in the amount of \$475.00 ·Petition for Extension of Time (3 months)			<b>CONFIDENTIAL</b>

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Andrew P. Kloeck et al. Art Unit : 1652  
Serial No. : 10/082,894 Examiner : Malgorzata A. Walicka  
Filed : February 26, 2002  
Title : NEMATODE PGM-LIKE SEQUENCES

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

PETITION FOR THREE-MONTH EXTENSION OF TIME

Pursuant to 37 CFR §1.136, applicant hereby petitions that the period for response to the action dated August 12, 2003, be extended for three months to and including February 12, 2004.

Enclosed is a check for \$475 for the required fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 2/12/04

John W. Meiklejohn Reg # 29,066  
John W. Meiklejohn, Ph.D.  
Reg. No. 35,283

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225 Franklin Street  
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Facsimile: (617) 542-8906

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February 12, 2004  
Date of Deposit

Carrie A. Amonte  
Signature

Carrie A. Amonte  
Typed or Printed Name of Person Signing Certificate





IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Andrew P. Kloeck et al.                      Art Unit : 1652  
Serial No. : 10/082,894                                      Examiner : Malgorzata A. Walicka  
Filed : February 26, 2002  
Title : NEMATODE PGM-LIKE SEQUENCES

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

AMENDMENT IN REPLY TO ACTION OF AUGUST 12, 2003

Please amend the above-identified application as follows:

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CERTIFICATE OF MAILING BY FIRST CLASS MAIL

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February 12, 2004  
Date of Deposit

Carrie A. Amonte  
Signature

Carrie A. Amonte  
Typed or Printed Name of Person Signing Certificate

Applicant : Andrew P. Kloeck et al.  
Serial No. : 10/082,894  
Filed : February 26, 2002  
Page : 2 of 9

Attorney's Docket No.: 12557-003001 / PGM

Amendments to the Specification:

Please replace the paragraph beginning at page 21, line 24 as with the following amended paragraph:

Functional predictions were made with PFAM (available on the ~~World Wide Web~~ Internet at ~~www~~.pfam.wustl.edu/), which is a Hidden Markov Model based database of families of protein domains. No hits were found in searches using either the *C. elegans* or *M. incognita* polypeptides as queries suggesting that these polypeptides are a novel class of PGM-like enzymes. Protein localization was predicted using the TargetP server (available on the Internet ~~World Wide Web~~ at ~~www~~.cbs.dtu.dk/services/TargetP). The *C. elegans* PGM was predicted to be mitochondrial and the *M. incognita* PGM was predicted to be cytosolic.

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1-4. (Canceled).

5. (Currently amended) An isolated nucleic acid molecule encoding a polypeptide comprising an amino acid sequence that is at least 80% identical to the amino acid sequence of SEQ ID NO:2, wherein the polypeptide has phosphoglycerate mutase activity.

6. (Currently amended) The isolated nucleic acid molecule of claim 5 wherein the amino acid sequence is at least 85% identical to the amino acid sequence of SEQ ID NO:2.

7-8. (Canceled).

9. (Currently amended) An isolated nucleic acid molecule comprising the nucleotide sequence of nucleotides 22 to 1599 of SEQ ID NO:1 ~~SEQ ID NO:3.~~

10. (Currently amended) The isolated nucleic acid molecule of claim 5, further comprising a heterologous promoter operably linked to the isolated nucleic acid.

11-18. (Canceled).

19. (Newly added) An isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:1.

20. (Newly added) The isolated nucleic acid molecule of claim 5 wherein the amino acid sequence is at least 90% identical to the amino acid sequence of SEQ ID NO:2.

21. (Newly added) The isolated nucleic acid molecule of claim 5 wherein the amino acid sequence is at least 95% identical to the amino acid sequence of SEQ ID NO:2.

22. (Newly added) The isolated nucleic acid molecule of claim 5 wherein the amino acid sequence is at least 98% identical to the amino acid sequence of SEQ ID NO:2.

23. (Newly added) A vector comprising the isolated nucleic acid molecule of any one of claims 5, 6, 9, 10 and 19-22.

24. (Newly added) The vector of claim 23 further comprising a heterologous promoter operably linked to the isolated nucleic acid molecule.

24. (Newly added) An isolated host cell comprising the isolated nucleic acid molecule of any one of claims 5, 6, 9, 10 and 19-22.

25. (Newly added) An isolated host cell comprising the vector of claim 23 or claim 24.

### REMARKS

The presently claimed invention features isolated nucleic acid molecule encoding a polypeptide comprising an amino acid sequence that is at least 80% identical to the amino acid sequence of SEQ ID NO:2 and has phosphoglycerate mutase activity.

SEQ ID NO:2 is the sequence amino acid sequence of an *M. incognita* phosphoglycerate mutase.

#### Objections to the Specification

Applicants have amended the specification in response to objections made by the Examiner.

#### Objections to the Claims

The Examiner state the claim 4 improperly depended from claim 4, which has been cancelled. Applicants believe that the Examiner meant to state that claim 8 improperly depended from claim 4. Claim 8 has been cancelled.

#### Rejections Under 35 U.S.C. §112, second paragraph

The Examiner rejected claim 8 as indefinite for referring to SEQ ID NO:3 as a nucleotide sequence. Claim 8 has been amended to refer to the open reading frame of SEQ ID NO:1. This amendment is supported by the specification, for example, at lines 27-29 of page 15. No new matter has been added.

#### Rejections Under 35 U.S.C. §112, first paragraph (written description)

The Examiner rejected claims 5, 6, 8 and 10 as allegedly failing to meet the written description requirement of 35 U.S.C. §112, first paragraph.

The Examiner stated that the claims do not state the function of the polypeptides encoded by the claimed genus of nucleic acid molecules. Claim 8 has been amended to specify that the

encoded polypeptide has phosphoglycerate mutase activity. Thus, present claim 8 is drawn to a purified polypeptide that: 1) comprises an amino acid sequence that is at least 80% identical to SEQ ID NO:2 (an *M. incognita* phosphoglycerate mutase); and 2) has phosphoglycerate mutase activity. Phosphoglycerate mutase (PGM) is an enzyme of the glycolytic and gluconeogenic pathways that catalyzes the interconversion of 3-phospho-D-glycerate [3-PGA] and 2-phospho-D-glycerate [2-PGA] in the Embden-Meyerhoff pathway. The present specification provides a detailed description of an *in vitro* assay that can be used to assess the ability of a polypeptide to catalyze the conversion of oxaloacetate to malate (see page 36 of the specification). The specification provides an assay for measuring phosphoglycerate mutase activity, see, e.g., page 40. Those of ordinary skill in the art know other such assays. Thus, those skilled in the art can determine whether a polypeptide, e.g., a polypeptide that comprises an amino acid sequence that is least 80% identical to SEQ ID NO:2 has phosphoglycerate mutase activity.

In *Regents of the University of California v. Eli Lilly & Co.*, the Court of Appeals for Federal Circuit held that an adequate written description of genetic material "requires a precise definition, such as by structure, formula, chemical name, or physical properties." 119 F.3d at 1563. The presently claimed nucleic acid molecules are defined by sequence or by sequence combined with function. Thus, the present claims meet the written description requirement as articulated by the court in *Eli Lilly*.

The Synopsis of Written Description Guidelines published by the United States Patent and Trademark Office (the "Guidelines") includes an example of a claim drawn to a protein defined by sequence (percent identity to a reference sequence) and function (ability to catalyze a particular reaction) and supported by a specification disclosing an assay for the specified function. The Guidelines state that such claims can meet the written description requirement. Here, the nucleic acid molecules encode polypeptide defined by sequence (percent identity a reference sequence, SEQ ID NO:2) and a function (phosphoglycerate mutase activity). These claims are supported by a specification disclosing an assay for the specified function. Thus, it is Applicants' position that the present claims meet the written description requirement as articulated in the prevailing case law and consistent with the USPTO's own guidelines.

In view of the forgoing, Applicants respectfully submit that the rejection based on the written description requirement of 35 U.S.C. §112, first paragraph be withdrawn.

Rejections Under 35 U.S.C. §112, first paragraph (enablement)

The Examiner rejected previously pending claims 5, 6, 8 and 10 as allegedly failing to failing to meet the enablement requirement of 35 U.S.C. §112, first paragraph.

Given the teachings of the specification, one skilled in the art could make and use the claimed nucleic acids without undue experimentation because the specification teaches one skilled in the art how to identify nucleic acid molecules encoding biologically active polypeptides. The Court of Appeals for the Federal Circuit has identified eight factors that must be considered in determining whether undue experimentation would be required to practice a claimed invention: "(1) the quantity of experimentation necessary, (2) the amount and direction of guidance provided, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *In re Wands*, 858 F.2d 731, 740 (Fed. Cir. 1988).

With respect to the relative skill in the art, it is clear that the relative skill in art of generating variant polypeptides is very high. For example, those skilled in the art are aware of various random mutagenesis protocols can be used to create libraries of clones encoding variant polypeptides.

With respect to the guidance provided by the specification, the Examiner argues that specification does not provide sufficient guidance to enable one of ordinary skill in that art to identify functional polypeptides within the scope of the claims.

Applicants disagree with the Examiner's assertion that the specification does not provide sufficient guidance regarding which regions of the polypeptide are important for activity and which amino acid substitutions are likely to be functional. The specification provides the amino acid sequences of two different phosphoglycerate mutase proteins (*C. elegans* and *M. incognita*). Figure 3 of the specification provides an alignment of amino acid sequence of these two proteins.

The sequence alignment of Figure 3 provides ample guidance to those of ordinary skill in art in creating functional polypeptides within the claims. Of course, in many case it is desirable to test the proteins for functional activity.

With respect to the absence or presence of working examples, the specification provides a working example of a *M. incognita* phosphoglycerate mutase

Regarding the breadth of the claims, it is Applicants' position that the claims are not excessively broad encompassing as they do nucleic acid molecules encoding polypeptides having at least 80% identity to a reference polypeptide (SEQ ID NO:2).

With respect to predictability, although it cannot always be predicted whether a given amino acid change will alter function, it is generally understood, despite some exceptions, that certain types of variants, e.g., those involving conservative amino acid substitutions are more likely to retain function. Moreover, the sequence alignment provided in Figure 3 of the application provides information that allows one to more predictably select functional polypeptides within the claims.

With respect to the amount of experimentation required, the guidance regarding conserved residues combined with the assays for phosphoglycerate mutase activity provided in the specification permit one to make and use the claimed invention without undue experimentation.

Consideration of the *Wands* factors leads to the conclusion that the specification enables one of ordinary skill in the art to make and to use the invention.

In view of the forgoing, Applicants respectfully request that the enablement rejections under 35 U.S.C. §112, first paragraph be withdrawn.



Applicant : Andrew P. Kloeck et al.  
Serial No. : 10/082,894  
Filed : February 26, 2002  
Page : 9 of 9

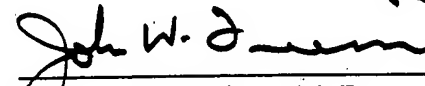
Attorney's Docket No.: 12557-003001 / PGM

Enclosed is a Petition for Extension of Time with the appropriate fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: \_\_\_\_\_

2/12/14

  
Anita L. Meiklejohn, Ph.D.  
Reg. No. 35,283

Reg # 29,166

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